

**SPECIAL 510(k): Device Modification**  
**OIVD Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE

**RE:** DOCUMENT NUMBER: k113343

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary) for the ***DiaCheck Smart and DiaCheck Superior Blood Glucose Monitoring Systems***:

1. The name and 510(k) number of SUBMITTER'S previously cleared device: ***DiaCheck Premium Blood Glucose Monitoring System; k100806***.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials. (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

**This change was for:**

- Addition of one button for the Superior model and elimination of one button for the Smart model.
  - Addition of strip ejection button to both Smart and Superior models
  - Decreased memory size of Smart model
  - Change in batteries from 2 AA to one 3V CR-2032 for both Smart and Superior models
  - Change in meter size (in mm) from 90(L)x60(W)x25(H) to 96(L)x35(W)x20(H) for the Smart model and to 83(L)x61(W)x23(H) for the Superior model
  - Software modification to both Smart and Superior models to modify the icon display on the LCD
  - Change in coding procedure for the Smart model, from selection of correct code via meter display to insertion of code strip into port in the meter
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics.
  5. A **Design Control Activities Summary** which includes:
    - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.
    - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
    - c) A declaration of conformity with design controls. The declaration of conformity should include:
      - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
  6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices)**.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the

particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

The devices are intended for single-patient use only. Super Sani-Cloth Germicidal Wipes with EPA registration # 9480-4 were validated demonstrating complete inactivation of live virus for use with the meters. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meters after 260 cleaning and disinfection cycles designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.